

REMARKS

Claims 1-16 are rejected. Claims 1 and 16 have been amended. New claim 28 has been added. Claims 17-22, 23-27 have been withdrawn. Claims 1-16 and 28 are presently pending in the application. Favorable reconsideration of the application in view of the following remarks is respectfully requested.

The basis for the amendment of claim 1 is found on pg. 1, line 7, pg. 4, line 24, and pg. 18, line 19 (specific binding) of the specification as originally filed. The basis for the amendment of claim 16 is claim 15 as originally filed. The basis for new claim 28 is found in claims 1, 9, 10, and 12 as originally filed, as well as pg. 7, lines 6-19 of the specification as originally filed.

Information Disclosure Statement

The Examiner indicated that the information disclosure statement entered on 11/10/2003 failed to comply with 37 CFR 1.98(a)(3) because it did not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It was placed in the application file, but the information referred to therein regarding citation A6 (Document number 95/04594) has not been considered. The concise explanation of the relevance of the reference may be found at page 2, lines 3-5 of the instant specification. Further, English Equivalents for Document number 95/04594 are US Patent No. 5,756,050 and 5,962,329 which are also included in the attached information disclosure statement. Consideration of each such reference is respectfully requested.

The Examiner indicated that the information data sheets entered 11/10/2003 and 1/21/2005 are objected to because dates are missing from the foreign patents documents [See MPEP 609.01, (B)(1)(e)(iv)]. Examiner has not initialed citations A2-A5, A7-A8 and B4 for this reason. The missing dates from the foreign patent documents have been entered on the attached information disclosure statement, and copies of each have been previously submitted and available to the Examiner in the electronic file record.

Rejection Under 35 U.S.C. §102(b):

The Examiner has rejected Claims 1, 2, 6, and 9-12 under 35 U.S.C. 102(b) as being anticipated by Dorogushin et al (Soviet Union Patent

SU308662), a translation of which has been provided herewith as Attachment B-1. The Examiner indicates that Dorogushin, et al, in the abstract teach a cellulose acetate film comprising two layers: a gelatin sublayer to improve adhesion which is applied with acetone, ethanol and phthalic acid and a copying layer, also comprising gelatin and, as it is well known in the art as evidenced by Schor et al (1996 J. Cell Sci. 109:2581-2590), fibronectin is a protein which binds denatured collagen (a.k.a. gelatin), inherently, the entirety of the gelatin based film of Dorogushin et al would perform as a protein microarray element, reading on "a gelatin layer containing functional groups capable of binding biological probes" of Claim 1. The Examiner states that the improved adhesive gelatin sublayer of Dorogushin et al reads on "an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer" of claim 1 part (c), and the gelatin adhesive interlayer of claim 6 (elected species) and claim 9, the cellulose acetate film of Dorogushin reads on the support of claim 1 part (a) and the organic support of claim 2, the ethanol and acetone of Dorogushin et al read on the "organic solvent or a mixture of solvents" of claim 10 and the acetone of claim 11 (elected species), and according to page 7 of the specification, an organic acid can act as dispersion aid, thus the phthalic acid of Dorogushin et al reads on the dispersing aid of Claim 12.

Dorogushina relates to a photosensitive copying material for gravure printing which has a film, a gelatin sublayer and a photosensitive copying layer containing gelatin and chromate.

As used by the Examiner, Schor discloses that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin).

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, located between the support and gelatin layer. The present invention also relates to a protein microarray element comprising a support, a gelatin layer containing functional groups capable of specific binding of biological probes and, interposed between the support and the gelatin layer, an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, wherein said

adhesive interlayer layer comprises gelatin, at least one organic solvent, a crosslinking agent, and a silicate salt.

A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. Dorogushina fails to expressly disclose a gelatin layer containing functional groups capable of specific binding of biological probes, which would be useful as protein microarray. Neither is the presence of functional groups in gelatin an inherent property capable of specific binding of biological probes. The present specification, pg. 18, line 16 – pg. 19, line 2, provides evidence that gelatin is a known, non-specific binder and the problems associated with its use in a protein microarray element. U.S. Pat. No. 6,797,393, col. 9, Example 5, illustrating the non-specific binding to protein of coated gelatin surfaces, also provides evidence that gelatin is known for non-specific binding of protein. The present claims require specific binding, as a result of the functional groupings on the gelatin. Since Dorogushina and Schor fail to teach, expressly or inherently, the use of a functionalized gelatin for specific binding of proteins, the reference fail to anticipate the present claims. The Applicants request that the Examiner reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §102(b):

The Examiner has rejected Claims 1, 2, 6, 9-10 and 12 under 35 U.S.C. 102(b) as being anticipated by Himmelmann et al (US Patent 3480431), indicating that Himmelmann et al teach a cellulose acetate film comprising two layers: a gelatin adhesive layer applied with 3 % formalin and di-isobutyl naphthalic-1-sulfonic acid and a grey layer, also comprising gelatin. The Examiner states that, since it is well known in the art and as evidenced by Schor et al (1996 J. Cell Sci. 109:2581-2590) that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin), inherently, the entirety of the gelatin based film of Himmelmann et al would perform as a protein microarray element,

reading on "a gelatin layer containing functional groups capable of binding biological probes". The Examiner continues that the adhesive gelatin layer of Himmelmann et al reads on "an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer", the gelatin adhesive interlayer of Claim 6 (elected species) and Claim 9, the cellulose acetate film of Himmelmann et al reads on the support of Claim 1 part (a) and the organic support of Claim 2, the formalin solution of Himmelmann et al reads on the "organic solvent or a mixture of solvents" of claim 10, and, according to page 7 of the specification of the instant application, an organic acid can act as dispersion aid, thus the di-isobutyl naphthalic-1-sulfonic acid of Himmelmann et al reads on the dispersing aid of Claim 12.

Himmelmann relates to a photographic material for a dry copying process, which material contains a uniformly dyed layer and an azopyrazolone.

As used by the Examiner, Schor discloses that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin).

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, located between the support and gelatin layer. The present invention also relates to a protein microarray element comprising a support, a gelatin layer containing functional groups capable of specific binding of biological probes, and, interposed between the support and the gelatin layer, an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, wherein said adhesive interlayer layer comprises gelatin, at least one organic solvent, a crosslinking agent, and a silicate salt.

A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between

the support and gelatin layer. Himmelmann fails to expressly disclose a gelatin layer containing functional groups capable of specific binding of biological probes, which would be useful as protein microarray. Neither is the presence of functional groups in gelatin an inherent property capable of specific binding of biological probes. The present specification, pg. 18, line 16 – pg. 19, line 2, provides evidence that gelatin is a known, non-specific binder and the problems associated with its use in a protein microarray element. U.S. Pat. No. 6, 797, 393, col. 9, Example 5, illustrating the non-specific binding to protein of coated gelatin surfaces, also provides evidence that gelatin is known for non-specific binding of protein. The present claims require specific binding, as a result of the functional groupings on the gelatin. Since Himmelmann and Schor fail to teach, expressly or inherently, the use of a functionalized gelatin for specific binding of proteins, the reference fail to anticipate the present claims. The Applicants request that the Examiner reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §102(b):

The Examiner has rejected Claims 1,2,6,9 and 15 under 35 U.S.C. 102(b) as being anticipated by Bauer et al (US Patent 5639589 - IDS entry 1/21/2005), as Bauer et al teach a polyethylene naphthalate film support comprising multiple layers including a gelatin adhesive layer and additional colored layers, also comprising gelatin. The Examiner indicates that, as is well known in the art and as evidenced by Schor et al (1996 J. Cell Sci. 109:2581-2590), fibronectin is a protein which binds denatured collagen (a.k.a. gelatin), thus inherently, the entirety of the gelatin based film of Bauer et al would perform as a protein microarray element, reading on "a gelatin layer containing functional groups capable of binding biological probes". The Examiner continues that the adhesive gelatin layer of Bauer et al reads on "an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer" of Claim 1 part (c), the gelatin adhesive interlayer of Claim 6 (elected species) and Claim 9. The polyethylene naphthalate film of Bauer et al reads on the support of claim 1 part (a) and the organic support of Claim 2, and Bauer et al teach that the gelatin layers are 2.44 g per square meter, reading on the microarray with gelatin coverage is 0.2 to 100 grams per square meter of Claim 15.

Bauer relates to polyester photographic film base and to photographic elements having a light-sensitive photographic layer on the film

base. In particular, the invention relates to a subbing layer for improving the adhesion of subsequently applied layers to polyester film base. A polyester photographic film support bears a subbing layer which comprises a mixture of gelatin and a polymer.

As used by the Examiner, Schor discloses that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin).

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, located between the support and gelatin layer. The present invention also relates to a protein microarray element comprising a support, a gelatin layer containing functional groups capable of specific binding of biological probes, and, interposed between the support and the gelatin layer, an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, wherein said adhesive interlayer layer comprises gelatin, at least one organic solvent, a crosslinking agent, and a silicate salt.

A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. Bauer fails to expressly disclose a gelatin layer containing functional groups capable of specific binding of biological probes, which would be useful as protein microarray. Neither is the presence of functional groups in gelatin an inherent property capable of specific binding of biological probes. The present specification, pg. 18, line 16 – pg. 19, line 2, provides evidence that gelatin is a known, non-specific binder and the problems associated with its use in a protein microarray element. U.S. Pat. No. 6,797,393, col. 9, Example 5, illustrating the non-specific binding to protein of coated gelatin surfaces, also provides evidence that gelatin is known for non-specific binding of

protein. The present claims require specific binding, as a result of the functional groupings on the gelatin. Since Bauer and Schor fail to teach, expressly or inherently, the use of a functionalized gelatin for specific binding of proteins, the reference fail to anticipate the present claims. The Applicants request that the Examiner reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §103(a):

The Examiner has rejected Claims 1,2,6,9-12,15 and 7, 8 under 35 U.S.C. 103(a) as being unpatentable over any of Dorogushin et al (Soviet Union Patent SU308662 - IDS entry 1/21/2005 transferred to PTO-892), Himmelmann et al (US Patent 3480431) or Bauer et al (US Patent 5639589 - IDS entry 1/21/2005), each taken separately, each in view of Roberts et al (US Patent 5380642), as the claimed invention is drawn to a protein microarray element comprising: a) a support; b) a gelatin layer containing functional groups capable of binding biological probes; and interposed between the support and the gelatin layer c) an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer and Dorogushin, et al, teach a cellulose acetate film comprising two layers: a gelatin sublayer to improve adhesion which is applied with acetone, ethanol and phthalic acid and a copying layer, also comprising gelatin, the improved adhesive gelatin sublayer of Dorogushin et al is taken to be "an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer" of Claim 1 part (c), the gelatin adhesive interlayer of claim 6 (elected species) and Claim 9, the cellulose acetate film of Dorogushin is taken to be the support of Claim 1 part (a) and the organic support of Claim 2, the ethanol and acetone of Dorogushin et al is taken to be the "organic solvent or a mixture of solvents" of Claim 10 and the acetone of Claim 11 (elected species) and, according to page 7 of the specification, an organic acid can act as dispersion aid, thus the phthalic acid of Dorogushin et al is taken to be the dispersing aid of Claim 12, Himmelmann et al teach a cellulose acetate film comprising two layers: a gelatin adhesive layer applied with 3 % formalin and di-isobutyl naphthalic-sulfonate and a grey layer, also comprising gelatin, the adhesive gelatin layer of Himmelmann et al is taken to be "an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer" of Claim 1 part (c), the gelatin adhesive interlayer of claim 6 (elected species) and Claim 9, the cellulose acetate film of Himmelmann et al is taken to be the support

of Claim 1 part (a) and the organic support of Claim 2, the formalin solution of Himmelmann et al is taken to be the "organic solvent or a mixture of solvents" of Claim 10, and according to page 7 of the specification of the instant application, an organic acid can act as dispersion aid, thus the di-isobutyl-naphthalic-1-sulfonic acid of Himmelmann et al is taken to be the dispersing aid of Claim 12, Bauer et al teach a polyethylene naphthalate film support comprising multiple layers including a gelatin adhesive layer and additional colored layers, also comprising gelatin, the adhesive gelatin layer of Bauer et al is taken to be "an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer" of Claim 1 part (c), and the gelatin adhesive interlayer of Claim 6 (elected species) and Claim 9, the polyethylene naphthalate film of Bauer et al is taken to be the support of Claim 1 part (a) and the organic support of Claim 2, and the gelatin layers are 2.44 g per square meter, which is taken to be the microarray with gelatin coverage is 0.2 to 100 grams per square meter of claim 15. The Examiner indicates that, as is well known in the art and as evidenced by Schor et al (1996 *J. Cell Sci.* 109:2581-2590), fibronectin is a protein which binds denatured collagen (a.k.a. gelatin), thus inherently, the entirety of the gelatin based film of Dorogushin, Himmelmann or Bauer would perform as a protein microarray element, which is taken to be the "a gelatin layer containing functional groups capable of binding biological probes" of Claim 1 part (b) as well as the preamble of Claim 1, and, although none of Dorogushin, Himmelmann or Bauer teach an adhesive layer comprising polyacrylamide or a synthetic polymeric peptizer, Roberts et al, teach the use of polyacrylamide based peptizers for gelatins, which is taken to be the "synthetic polymeric peptizers" of Claim 7 (elected species) and "adhesive interlayer comprising acrylamide polymers" of Claim 8 (elected species), making it *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use the polyacrylamide based peptizers in preparing the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer. In addition, the Examiner states that one of ordinary skill in the art would have been motivated to make and use the polyacrylamide based peptizers of Roberts et al with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer because the arrays would have had better resistance to bacterial decomposition and provided easier handling in non aqueous environments, as

noted by Roberts et al in column 2, lines 35 and 45 and one of ordinary skill in the art could have used the polyacrylamide based peptizers of Roberts et al with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer with a reasonable expectation of success based on the many examples provided by Roberts et al.

Dorogushina relates to a photosensitive copying material for gravure printing which has a film, a gelatin sublayer and a photosensitive copying layer containing gelatin and chromate.

As used by the Examiner, Schor discloses that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin).

Himmelmann relates to a photographic material for a dry copying process, which material contains a uniformly dyed layer and an azopyrazolone.

Bauer relates to polyester photographic film base and to photographic elements having a light-sensitive photographic layer on the film base. In particular, the invention relates to a subbing layer for improving the adhesion of subsequently applied layers to polyester film base. A polyester photographic film support bears a subbing layer which comprises a mixture of gelatin and a polymer.

Roberts relates in general to photography and in particular to the preparation of silver halide emulsions that are useful in photography. More specifically, this invention relates to a novel process for preparing a thin tabular grain silver halide emulsion by nucleating the silver halide grains with a gelatino-peptizer or with the use of certain synthetic polymers that serve as effective nucleation peptizers and then growing the silver halide grains with the use of either a gelatino-peptizer or certain synthetic polymers that serve as effective growth peptizers.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, located between the support and gelatin layer. The present invention also relates to a protein microarray element comprising a support, a gelatin layer containing functional groups capable of specific binding of biological probes, and, interposed between the support and the gelatin layer, an adhesive interlayer layer capable of

maintaining contact with the support and with the gelatin layer, wherein said adhesive interlayer layer comprises gelatin, at least one organic solvent, a crosslinking agent, and a silicate salt.

To establish a *prima facia* case of obviousness, there must be some suggestion or motivation in the reference or in the general knowledge available to one skilled in the art to modify the reference, there must be a reasonable expectation of success, and the prior art reference must teach or suggest all the claim limitations.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. As discussed above, none of Dorogushina, Himmelmann and Bauer, alone or combined with Schor, teach a gelatin layer containing functional groups capable of specific binding of biological probes, which would be useful as protein microarray. Roberts also fails to teach or suggest the use of a gelatin layer containing functional groups capable of specific binding of biological probes. None of the references relate to protein microarrays and none of the references teach a gelatin layer containing functional groups capable of specific binding of biological probes as presently claimed.

The references also provide no likelihood of success in the use of a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer as a protein microarray. The present specification, pg. 18, line 16 – pg. 19, line 2, provides evidence that gelatin is a known, non-specific binder and the problems associated with its use in a protein microarray element. U.S. Pat. No. 6,797,393, col. 9, Example 5, illustrating the non-specific binding to protein of coated gelatin surfaces, also provides evidence that gelatin is known for non-specific binding of protein. Therefore the references provide no likelihood of success for the use of gelatin, a known non-specific binder, as a component in a layer capable of specific binding of biological probes.

The present claims require specific binding, as a result of the functional groupings on the gelatin. Himmelmann, Dorogushina and Bauer, with

Schor, and in light of Roberts, fail to disclose the use of a functionalized gelatin for specific binding of proteins as presently claimed. Therefore, the references fail to disclose all of the limitations of the present claims.

In addition, the present invention provides surprising results. As previously discussed, gelatin is a known, non-specific binder of protein to a coated surface. In addition, as shown in Table 3, col. 10 of U.S. Pat. No. 6, 797, 393, gelatin has a lower non-specific binding capacity than other materials, that is, gelatin is not a very good non-specific binding material. Therefore, it would be surprising to one of ordinary skill in the art to select gelatin for use as a binder of protein on a coated surface, let alone to produce a highly specific binding material.

Therefore, since the references fail to provide a motivation to combine resulting in the presently claimed invention, fail to provide any likelihood of success, fail to include all the limitations of the present claims, and, in light of surprising results, the Applicants believe the references, alone or in combination, fail to make the present invention obvious and request that the Examiner reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §103(a):

The Examiner has rejected Claims 1, 2, 6, 9-12, 15 and 3-5 under 35 U.S.C. 103(a) as being unpatentable over any of Dorogushin et al (Soviet Union Patent SU308662 - IDS entry 1/21/2005 transferred to PTO-892), Himmelmann et al (US Patent 3480431) or Bauer et al (US Patent 5639589 - IDS entry 1/21/2005), each taken separately, each in view of Arenkov et al (2000 Analytical Biochemistry 278:123-131- IDS entry 11/10/2003 transferred to PTO-892), as Claim 3 limits the support to glass or fused silica, Claim 4 limits the substrate thickness to between 0.1 and 5 mm, Claim 5 limits the support to thickness to between 0.5 and 2.0 mm, Claim 12 includes the limitation that the adhesive layer comprise a crosslinker, but Dorogushin et al, Himmelmann et al, and Bauer et al are relied on as above and, although none of Dorogushin, Himmelmann or Bauer teach glass slide substrates, with a substrate thickness between 0.1 and 2.0 mm, or the introduction of a crosslinker however, Arenkov et al, teach throughout the publication, and especially page 124 under subheading Fabrication of gel micromatrices, the use of a Corning Micro Slide, which is taken to be the glass support of Claim 3 and further taken to be the inorganic support of

Claim 2, as evidenced by the Fisher Scientific Catalog (a printout from the on-line version is included with this Office Action), said slides are between 0.9 and 1.1 mm, which is taken to be in range the set forth in both Claims 4 and 5. Arenkov et al also teach the use of bisacrylamide as a crosslinker, making it *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use the Corning Micro Slide and employing bisacrylamide as a crosslinker of Arenkov et al with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer, as one of ordinary skill in the art would have been motivated to use the Corning Micro Slide and employing bisacrylamide as a crosslinker of Arenkov et al with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer because the transparency of the slides and resulting polymer comprising bisacrylamide crosslinker would have afforded the ability to perform fluorescence, as noted by Arenkov in Figure 1, making the microarrays more versatile and one of ordinary skill in the art could have used the Corning Micro Slide employing bisacrylamide as a crosslinker of Arenkov et al with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer with a reasonable expectation of success since derivitization of glass slides is very well known in the art.

Dorogushina relates to a photosensitive copying material for gravure printing which has a film, a gelatin sublayer and a photosensitive copying layer containing gelatin and chromate.

As used by the Examiner, Schor discloses that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin).

Himmelmann relates to a photographic material for a dry copying process, which material contains a uniformly dyed layer and an azopyrazolone.

Bauer relates to polyester photographic film base and to photographic elements having a light-sensitive photographic layer on the film base. In particular, the invention relates to a subbing layer for improving the adhesion of subsequently applied layers to polyester film base. A polyester photographic film support bears a subbing layer which comprises a mixture of gelatin and a polymer.

Arenkov relates to the use of a modified polyacrylamide gel in a protein microchip.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. The present invention also relates to a protein microarray element comprising a support, a gelatin layer containing functional groups capable of specific binding of biological probes, and, interposed between the support and the gelatin layer, an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, wherein said adhesive interlayer layer comprises gelatin, at least one organic solvent, a crosslinking agent, and a silicate salt.

To establish a *prima facia* case of obviousness, there must be some suggestion or motivation in the reference or in the general knowledge available to one skilled in the art to modify the reference, there must be a reasonable expectation of success, and the prior art reference must teach or suggest all the claim limitations.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. As discussed above, none of Dorogushina, Himmelmann and Bauer, alone or combined with Schor, teach a gelatin layer containing functional groups capable of specific binding of biological probes, which would be useful as protein microarray. Arenkov also fails to teach or suggest the use of a gelatin layer containing functional groups capable of specific binding of biological probes, teaching instead a polyacrylamide gel layer. None of the references teach a gelatin layer containing functional groups capable of specific binding of biological probes as presently claimed.

The references also provide no likelihood of success in the use of a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer as a protein microarray. The present specification, pg. 18, line 16 – pg. 19, line 2, provides evidence that gelatin is a known, non-

specific binder and the problems associated with its use in a protein microarray element. U.S. Pat. No. 6, 797, 393, col. 9, Example 5, illustrating the non-specific binding to protein of coated gelatin surfaces, also provides evidence that gelatin is known for non-specific binding of protein. Arenkov provides no likelihood of success with the use of gelating, as teaches the use of a polyacrylamide gel layer. Therefore the references provide no likelihood of success for the use of gelatin, a known non-specific binder, as a component in a layer capable of specific binding of biological probes.

The present claims require specific binding, as a result of the functional groupings on the gelatin. Himmelmann, Arenkov, Dorogushina and Bauer, with Schor, fail to disclose the use of a functionalized gelatin for specific binding of proteins as presently claimed. Therefore, the references fail to disclose all of the limitations of the present claims.

In addition, the present invention provides surprising results. As previously discussed, gelatin is a known, non-specific binder of protein to a coated surface. In addition, as shown in Table 3, col. 10 of U.S. Pat. No. 6, 797, 393, gelatin has a lower non-specific binding capacity than other materials, that is, gelatin is not a very good non-specific binding material. Therefore, it would be surprising to one of ordinary skill in the art to select gelatin for use as a binder of protein on a coated surface, let alone to produce a highly specific binding material.

Therefore, since the references fail to provide a motivation to combine resulting in the presently claimed invention, fail to provide any likelihood of success, fail to include all the limitations of the present claims, and, in light of surprising results, the Applicants believe the references, alone or in combination, fail to make the present invention obvious and request that the Examiner reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §103(a):

The Examiner has rejected Claims 1, 2, 6, 9-12, 15 and 13 under 35 U.S.C. 103(a) as being unpatentable over any of Dorogushin et al (Soviet Union Patent SU308662 - IDS entry 1/21/2005 transferred to PTO-892), Himmelmann et al (US Patent 3480431) or Bauer et al (US Patent 5639589 - IDS entry 1/21/2005), each taken separately, each in view of Christopher (US Patent 2309340), as Claim 13 limits the gelatin to being alkaline pretreated and

Dorogushin et al, Himmelmann et al, and Bauer et al are relied on as above, and, although none of Dorogushin, Himmelmann or Bauer teach alkaline pretreated gelatin, Christopher teaches alkaline pretreatment of gelatin, making it *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use the alkaline pretreated gelatin of Christopher in making the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer, as one of ordinary skill in the art would have been motivated to use the alkaline pretreated gelatin of Christopher in making the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer because the alkaline pretreatment would have enhanced the adhesive (glue-like) properties of the gelatin, as noted by Christopher and one of ordinary skill in the art could have used the alkaline pretreated gelatin of Christopher with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer with a reasonable expectation of success since the advantage of alkaline pretreatment of gelatin has been appreciated in this and other arts for some time.

Dorogushina relates to a photosensitive copying material for gravure printing which has a film, a gelatin sublayer and a photosensitive copying layer containing gelatin and chromate.

As used by the Examiner, Schor discloses that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin).

Himmelmann relates to a photographic material for a dry copying process, which material contains a uniformly dyed layer and an azopyrazolone.

Bauer relates to polyester photographic film base and to photographic elements having a light-sensitive photographic layer on the film base. In particular, the invention relates to a subbing layer for improving the adhesion of subsequently applied layers to polyester film base. A polyester photographic film support bears a subbing layer which comprises a mixture of gelatin and a polymer.

Christopher relates to a method of extracting gelatinous material from gelatinous material stock such as hide trimmings, fleshings, sinews, and the like.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of

specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. The present invention also relates to a protein microarray element comprising a support, a gelatin layer containing functional groups capable of specific binding of biological probes, and, interposed between the support and the gelatin layer, an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, wherein said adhesive interlayer layer comprises gelatin, at least one organic solvent, a crosslinking agent, and a silicate salt.

To establish a *prima facia* case of obviousness, there must be some suggestion or motivation in the reference or in the general knowledge available to one skilled in the art to modify the reference, there must be a reasonable expectation of success, and the prior art reference must teach or suggest all the claim limitations.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. As discussed above, none of Dorogushina, Himmelmann and Bauer, alone or combined with Schor, teach a gelatin layer containing functional groups capable of specific binding of biological probes, which would be useful as protein microarray. Christopher also fails to teach or suggest the use of a gelatin layer containing functional groups capable of specific binding of biological probes, teaching only that gelatin can be used as an adhesive layer. None of the references relate to protein microarrays and none of the references teach a gelatin layer containing functional groups capable of specific binding of biological probes as presently claimed.

The references also provide no likelihood of success in the use of a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer as a protein microarray. The present specification, pg. 18, line 16 – pg. 19, line 2, provides evidence that gelatin is a known, non-specific binder and the problems associated with its use in a protein microarray

element. U.S. Pat. No. 6, 797, 393, col. 9, Example 5, illustrating the non-specific binding to protein of coated gelatin surfaces, also provides evidence that gelatin is known for non-specific binding of protein. Therefore the references provide no likelihood of success for the use of gelatin, a known non-specific binder, as a component in a layer capable of specific binding of biological probes.

The present claims require specific binding, as a result of the functional groupings on the gelatin. Himmelmann, Dorogushina and Bauer, with Schor, and in light of Christopher, fail to disclose the use of a functionalized gelatin for specific binding of proteins as presently claimed. Therefore, the references fail to disclose all of the limitations of the present claims.

In addition, the present invention provides surprising results. As previously discussed, gelatin is a known, non-specific binder of protein to a coated surface. In addition, as shown in Table 3, col. 10 of U.S. Pat. No. 6, 797, 393, gelatin has a lower non-specific binding capacity than other materials, that is, gelatin is not a very good non-specific binding material. Therefore, it would be surprising to one of ordinary skill in the art to select gelatin for use as a binder of protein on a coated surface, let alone to produce a highly specific binding material.

Therefore, since the references fail to provide a motivation to combine resulting in the presently claimed invention, fail to provide any likelihood of success, fail to include all the limitations of the present claims, and, in light of surprising results, the Applicants believe the references, alone or in combination, fail to make the present invention obvious and request that the Examiner reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §103(a):

The Examiner has rejected Claims 1, 2, 6, 9-12 and 14 under 35 U.S.C. 103(a) as being unpatentable over either of Dorogushin et al (Soviet Union Patent SU308662 - IDS entry 1/21/2005 transferred to PTO-892), Himmelmann et al (US Patent 3480431) or Bauer et al (US Patent 5639589 - IDS entry 1/21/2005), each taken separately, in view of Bonderman (US Patent 5348852), since Dorogushin et al, Himmelmann et al, and Bauer et al are relied on as above and, although none of Dorogushin, Himmelmann or Bauer teach pig or fish gelatin, Bonderman teach pig and fish gelatin, making it *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use

the fish gelatin of Bonderman in making the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer, as one of ordinary skill in the art would have been motivated to use the fish gelatin of Bonderman with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer because fish gelatin had been shown to better stabilize enzymes, giving the arrays a better shelf life and one of ordinary skill in the art could have used the fish gelatin of Bonderman with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer with a reasonable expectation of success since Bonderman provides examples from two different enzyme classes.

Dorogushina relates to a photosensitive copying material for gravure printing which has a film, a gelatin sublayer and a photosensitive copying layer containing gelatin and chromate.

As used by the Examiner, Schor discloses that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin).

Himmelmann relates to a photographic material for a dry copying process, which material contains a uniformly dyed layer and an azopyrazolone.

Bauer relates to polyester photographic film base and to photographic elements having a light-sensitive photographic layer on the film base. In particular, the invention relates to a subbing layer for improving the adhesion of subsequently applied layers to polyester film base. A polyester photographic film support bears a subbing layer which comprises a mixture of gelatin and a polymer.

Bonderman relates to improved compositions such as medical and diagnostic compositions, and to methods of their preparation and use. The improved compositions are highly stable and have desirable physical and chemical properties. The compositions comprise an effective amount of gelatin from cold water fish skin as a protein base.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. The present invention also relates to a protein microarray element comprising a support, a gelatin layer containing functional

groups capable of specific binding of biological probes, and, interposed between the support and the gelatin layer, an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, wherein said adhesive interlayer layer comprises gelatin, at least one organic solvent, a crosslinking agent, and a silicate salt.

To establish a *prima facia* case of obviousness, there must be some suggestion or motivation in the reference or in the general knowledge available to one skilled in the art to modify the reference, there must be a reasonable expectation of success, and the prior art reference must teach or suggest all the claim limitations.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. As discussed above, none of Dorogushina, Himmelmann and Bauer, alone or combined with Schor, teach a gelatin layer containing functional groups capable of specific binding of biological probes, which would be useful as protein microarray. Bonderman also fails to teach or suggest the use of a gelatin layer containing functional groups capable of specific binding of biological probes. None of the references relate to protein microarrays and none of the references teach a gelatin layer containing functional groups capable of specific binding of biological probes as presently claimed.

The references also provide no likelihood of success in the use of a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer as a protein microarray. The present specification, pg. 18, line 16 – pg. 19, line 2, provides evidence that gelatin is a known, non-specific binder and the problems associated with its use in a protein microarray element. U.S. Pat. No. 6,797,393, col. 9, Example 5, illustrating the non-specific binding to protein of coated gelatin surfaces, also provides evidence that gelatin is known for non-specific binding of protein. Therefore the references provide no likelihood of success for the use of gelatin, a known non-specific binder, as a component in a layer capable of specific binding of biological probes. In

addition, Bonderman is associated with a fish gelatin. The benefits of this gelatin appear to be its labile nature and its resistance to gelation. See col. 1, lines 54-56; see also col. 2, lines 26-29. The present invention utilizes at least one layer of gelatin. The gelatin of Bonderman would not produce a layer of gelatin on the support. See col. 5, lines 53-55. If fish gelatin were used in conjunction with the other references, no layer structure would be produced, rendering the references inoperable for their intended uses.

The present claims require specific binding, as a result of the functional groupings on the gelatin. Himmelmann, Dorogushina and Bauer, with Schor, and in light of Christopher, fail to disclose the use of a functionalized gelatin for specific binding of proteins on a support as presently claimed. Therefore, the references fail to disclose all of the limitations of the present claims.

In addition, the present invention provides surprising results. As previously discussed, gelatin is a known, non-specific binder of protein to a coated surface. In addition, as shown in Table 3, col. 10 of U.S. Pat. No. 6, 797, 393, gelatin has a lower non-specific binding capacity than other materials, that is, gelatin is not a very good non-specific binding material. Therefore, it would be surprising to one of ordinary skill in the art to select gelatin for use as a binder of protein on a coated surface, let alone to produce a highly specific binding material.

Therefore, since the references fail to provide a motivation to combine resulting in the presently claimed invention, fail to provide any likelihood of success, fail to include all the limitations of the present claims, and, in light of surprising results, the Applicants believe the references, alone or in combination, fail to make the present invention obvious and request that the Examiner reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §103(a):

The Examiner has rejected Claims 1, 2, 6 and 9-12 under 35 U.S.C. 103(a) as being unpatentable over either of Dorogushin et al (Soviet Union Patent SU308662 - IDS entry 1/21/2005 transferred to PTO-892), Himmelmann et al (US Patent 3480431), each taken separately, in view of Fiebag (US Patent 6143479), since Dorogushin et al, Himmelmann et al, are relied on as above and, although neither of Dorogushin or Himmelmann teach sodium silicate as a

dispersing aid, Fiebag teach water glass (a.k.a. sodium silicate) as a conventional wetting or dispersive agent, which is taken to be the ciliate salt of Claim 12, making it would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use a silicate salt as a dispersion aid in preparing the gelatin based films capable performing as protein microarrays of Dorogushin or Himmelmann employment of a silicate salt, as opposed to the organic acid based dispersion aids described above by Dorogushin et al or Himmelmann et al represents a routine experimental optimization and the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation and one of ordinary skill could employ silicate salts, in preparing the gelatin based films capable performing as protein microarrays of Dorogushin or Himmelmann, with a reasonable expectation of success since their properties as dispersive aids has been well appreciated in this and other arts for some time.

Dorogushina relates to a photosensitive copying material for gravure printing which has a film, a gelatin sublayer and a photosensitive copying layer containing gelatin and chromate.

As used by the Examiner, Schor discloses that fibronectin is a protein which binds denatured collagen (a.k.a. gelatin).

Himmelmann relates to a photographic material for a dry copying process, which material contains a uniformly dyed layer and an azopyrazolone.

Bauer relates to polyester photographic film base and to photographic elements having a light-sensitive photographic layer on the film base. In particular, the invention relates to a subbing layer for improving the adhesion of subsequently applied layers to polyester film base. A polyester photographic film support bears a subbing layer which comprises a mixture of gelatin and a polymer.

Fiebag relates to developing systems useful for developing either positive-working or negative-working alkaline- developable lithographic printing plates including thermal plates. It also relates to a method for developing imagewise exposed printing plates. In Fiebag, an aqueous alkaline composition comprises at least one phosphonic acid, at least one polyglycol derivative and at least one glycol.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. The present invention also relates to a protein microarray element comprising a support, a gelatin layer containing functional groups capable of specific binding of biological probes, and, interposed between the support and the gelatin layer, an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer, wherein said adhesive interlayer layer comprises gelatin, at least one organic solvent, a crosslinking agent, and a silicate salt.

The reference to Fiebag cited by the Examiner comprises non-analogous art. In order to rely on a reference as a basis for rejection of Applicant's invention, a reference must either be in the field of the Applicant's endeavor or reasonably pertain to the particular problem with which the invention is concerned. Here, the cited reference to Fiebag is not in Applicant's field of endeavor, that is, a protein microarray element comprising a support, a gelatin layer containing functional groups capable of specific binding and of biological probes, with an adhesive interlayer layer. Neither is the reference reasonably pertinent to a protein microarray element or the specific binding and of biological probes by a layer of functionalized gelatin, since Fiebag deals with a developer or replenisher for lithographic printing.

Patent and Trademark Office Classification is some evidence of analogy, but similarities and differences in structure and function carry more weight. MPEP 2141.01(a). The reference to Fiebag cited by the Examiner is contained in US Class 430/331 (RADIATION IMAGERY CHEMISTRY: PROCESS, COMPOSITION, OR PRODUCT THEREOF / Finishing or perfecting composition or product), while the present invention is classified in US Class 435/006 (Chemistry: molecular biology and microbiology / Involving nucleic acid). Critical differences exist in function between Applicant's invention and the cited reference. The invention of Fiebag functions to develop lithographic printing plates and the inclusion of the additional ingredient alkali metal waterglass is used to prevent the attack of alumina and aluminum. Unlike the reference, the present invention functions to specifically bind biological probes in

a protein microarray and the silicate salt is used to enhance the adhesive strength of the interlayer (pg. 7, line 12).

Further there are important structural differences between the present invention and the prior art which are evidence of non-analogousness. The developer composition of Fiebag, including additives, is an aqueous alkaline developer or replenisher solution. The present invention is a protein microarray in which a series of layers is applied to a support, the adhesive layer of which may contain a silicate compound. To use the developer, printing plates are washed in developer solution. The present invention is a support-based gelatin receiver to biological materials, not a washing solution. Since the cited reference and the present invention are contained in different Classifications, serve a different purpose and function and contain distinct structural differences, the Applicants respectfully suggest that the cited reference is non-analogous art, and do not support a rejection based on obviousness.

Assuming for argument, that the cited references are analogous art, consideration must be given to Applicant's invention and the references as suggested by the Examiner, when taken as a whole. To establish a *prima facia* case of obviousness, there must be some suggestion or motivation in the reference or in the general knowledge available to one skilled in the art to modify the reference, there must be a reasonable expectation of success, and the prior art reference must teach or suggest all the claim limitations.

The present invention relates to a protein microarray element comprising a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer. As discussed above, none of Dorogushina, Himmelmann and Bauer, alone or combined with Schor, teach a gelatin layer containing functional groups capable of specific binding of biological probes, which would be useful as protein microarray. Fiebag also fails to teach or suggest the use of a gelatin layer containing functional groups capable of specific binding of biological probes. None of the references relate to protein microarrays and none of the references teach a gelatin layer containing functional groups capable of specific binding of biological probes as presently claimed.

The references also provide no likelihood of success in the use of a support and a gelatin layer containing functional groups capable of specific binding of biological probes, with an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer located between the support and gelatin layer as a protein microarray. The present specification, pg. 18, line 16 – pg. 19, line 2, provides evidence that gelatin is a known, non-specific binder and the problems associated with its use in a protein microarray element. U.S. Pat. No. 6, 797, 393, col. 9, Example 5, illustrating the non-specific binding to protein of coated gelatin surfaces, also provides evidence that gelatin is known for non-specific binding of protein. Therefore the references provide no likelihood of success for the use of gelatin, a known non-specific binder, as a component in a layer capable of specific binding of biological probes.

The present claims require specific binding, as a result of the functional groupings on the gelatin in a layer series on a support. Himmelmann, Dorogushina and Bauer, with Schor, and in light of Fiebag, fail to disclose the use of a functionalized gelatin for specific binding of proteins as presently claimed. Therefore, the references fail to disclose all of the limitations of the present claims.

In addition, the present invention provides surprising results. As previously discussed, gelatin is a known, non-specific binder of protein to a coated surface. In addition, as shown in Table 3, col. 10 of U.S. Pat. No. 6, 797, 393, gelatin has a lower non-specific binding capacity than other materials, that is, gelatin is not a very good non-specific binding material. Therefore, it would be surprising to one of ordinary skill in the art to select gelatin for use as a binder of protein on a coated surface, let alone to produce a highly specific binding material.

Therefore, since the references fail to provide a motivation to combine resulting in the presently claimed invention, fail to provide any likelihood of success, fail to include all the limitations of the present claims, and, in light of surprising results, the Applicants believe the references, alone or in combination, fail to make the present invention obvious and request that the Examiner reconsider and withdraw the rejection.

Double Patenting Rejection

The Examiner has provisionally rejected Claims 1-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/682271 in view of any of Dorogushin et al (Soviet Union Patent SU308662 - IDS entry 1/21/2005 transferred to PTO-892), Himmelmann et al (US Patent 3480431) or Bauer et al (US Patent 5639589 - IDS entry 1/21/2005). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) and signed by registered attorney or agent of record has been included to overcome the provisional rejection over commonly owned Application No. 10/682271.

Rejection Under 35 USC § 112:

The Examiner has rejected Claims 1 and dependent Claims 2-15 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, as Claim 1 recites vague and indefinite language in "interposed", since it is not clear as to whether the protein binding layer is on top or rather sandwiched between the substrate and adhesive layer. OneLook®.Dictionary Search indicates that the term "interposed" is a verb meaning "be or come between" or "to insert between other elements". The language of the claim indicates "and interposed between the support and the gelatin layer c) an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer", that is, inserted between other elements, an adhesive interlayer layer capable of maintaining contact with the support and with the gelatin layer. One of ordinary skill, using the plain meaning of the language of the claim would understand that the adhesive interlayer c) is between the support and the gelatin layer b). Therefore, the Applicants believe the rejection should be reconsidered and withdrawn.

Rejection Under 35 USC § 112:

The Examiner has rejected Claim 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as unlike Claim 15, the unit of measure concerning gelatin mass in claim 16 does not indicate the coverage area. Claim 16 has been amended accordingly.

It is believed that the foregoing is a complete response to the Office Action and that the claims are in condition for allowance. Favorable reconsideration and early passage to issue is therefore earnestly solicited.

Respectfully submitted,



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If the Examiner is unable to reach the Applicant(s) Attorney at the telephone number provided, the Examiner is requested to communicate with Eastman Kodak Company Patent Operations at (585) 477-4656.